K093810

Section 5 - 510(k) Summary

For

JUN 18 2010

Bf-NAVI

1. Sponsor Information

KGT Inc.
Tomin Shinjuku Bldg. 2-8-8, Shinjuku, Shinjuku-ku
Tokyo 160-0022
JAPAN
Phone: (81) 3-3225-0744
Fax: (81) 3-3225-0950
Contact: Kouichi Mansei, Manager

2. Applicant Information

Emergo Group
1705 S. Capital of Texas Highway
Suite 500
Austin, TX 78746
Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Richard Vincins, Senior Consultant QA/RA

3. Date Prepared

22 April 2010

4. Device Name

Trade/Proprietary Name: Bf-NAVI
Common/Usual Name: Bf-NAVI, Virtual Bronchoscopy Image Editor/Viewer
Classification Name: Computed tomography x-ray system
Classification Regulation: 892.1750
Product Code: JAK

5. Predicate Devices

VIDA Diagnostics – VIDA Pulmonary Workstation 2 (PW2) K083227
Olympus Medical Systems Corp – VB Image Viewer K080581
superDimension, Inc. – superDimension®/Bronchus K080271

6. Device Description

Bf-NAVI is a virtual bronchoscopic navigation (VBN) software program designed to assist a physician during a bronchoscopic examination. The main purpose of the software is to generate a tracheobronchial tree using chest CT scan data in order to help the physician find an optimal bronchial route to the target region. Bf-NAVI allows the physician to view a 3D representation of the bronchial tree that displays virtual images of the inside surface of the bronchi. Bf-NAVI is intended for use only as a guidance tool and does not make any medical diagnosis.

The Bf-NAVI software is a self-contained Windows-based image software package. Using pulmonary CT slice data, the Bf-NAVI device helps the user in guiding endoscopic tools or catheters in the pulmonary tract. The Bf-NAVI allows the user to view computed tomography via Multi-Planar Reconstruction (MPR). The software uses the CT data to generate a 3D image of the tracheobronchial tree. The Bf-NAVI device does not interface directly with any CT or data collection equipment; the CT data is imported from files previously created on another device.

The software does not perform any function which can not be accomplished manually by a trained operator utilizing manual tracing methods; the software is designed to assist in the compilation of the data to save time and prevent errors. The Bf-NAVI software has functions for loading, analyzing, saving data profiles and will generate screen displays from the results.

7. Intended Use

Bf-NAVI is a virtual bronchoscopic navigation (VBN) software program designed to assist a physician during a bronchoscopic examination. The main purpose of the software is to generate a tracheobronchial tree using chest CT scan data in order to help the physician find an optimal bronchial route to the target region. Bf-NAVI allows the physician to view a 3D representation of the bronchial tree that displays virtual images of the inside surface of the bronchi. Bf-NAVI is intended for use only as a guidance tool and does not make any medical diagnosis.

8. Technological Characteristics and Substantial Equivalence

The Bf-NAVI device shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices. The Bf-NAVI device is similar in design and function to the predicate devices for the modes of operation and use.

The Bf-NAVI software is a self-contained Windows-based image software package. The Bf-NAVI device is designed to capture pulmonary CT slice data and display results for the user in guiding endoscopic tools or catheters in the pulmonary tract. The Bf-NAVI provides computed tomography viewing via Multi-Planar Reconstruction (MPR) to generate the three-dimensional image. The Bf-NAVI device does not interface directly with any CT or data collection equipment; the software imports the data files previously generated. These devices all have the same intended use and indications for use as the Bf-NAVI device.

9. Non-Clinical Testing

The device's software development, verification, and validation have been carried out in accordance with FDA guidelines. The software was tested against the established Software Design Specifications for each of the test plans to assure the device performs as intended. The Device Hazard analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria of each module and interaction of processes. The Bf-NAVI device passed all testing and supports the claims of substantial equivalence and safe operation.

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate devices. The safety and efficacy of the device is supported by the non-clinical testing. The verification and validation testing of the device software of the device was found to acceptable and supports the claims of substantial equivalence.

11. Conclusion

The Bf-NAVI device has the same intended use and technological characteristics as the predicate devices.

The information provided in this submission supports the substantial equivalence to the predicate device and that the system is safe and effective for the users/operators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JUL 14 2010

KGT, Inc.
% Mr. Richard Vincins, CQA, RAC (US, EU)
Senior Consumer QA/RA
Emergo Group
1705 S. Capital of Texas Hwy., Suite 500
AUSTIN TX 78746

Re: K093810
Trade/Device Name: Bf-NAVI
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: June 4, 2010
Received: June 8, 2010

Dear Mr. Vincins:

This letter corrects our substantially equivalent letter of June 18, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Section 4 - Indications for Use

510(k) Number (if known): K093810

Device Name: Bf-NAVI

Indications for Use:

Bf-NAVI is a virtual bronchoscopic navigation (VBN) software program designed to assist a physician during a bronchoscopic examination. The main purpose of the software is to generate a tracheobronchial tree using chest CT scan data in order to help the physician find an optimal bronchial route to the target region. Bf-NAVI allows the physician to view a 3D representation of the bronchial tree that displays virtual images of the inside surface of the bronchi. Bf-NAVI is intended for use only as a guidance tool and does not make any medical diagnosis.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)
AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)_____

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K093810